

**Pediatric Advisory Committee Meeting****November 27, 2006**

Hilton Washington DC North/Gaithersburg, Grand Ballroom,  
620 Perry Parkway, Gaithersburg, Maryland

8:00AM	Welcome and Introductory Remarks	Marsha Rappley, MD Chair Dean, College of Human Medicine Michigan State University
		Carlos Peña, PhD, MS Executive Secretary Office of Science and Health Coordination OC, FDA
8:10	Agenda Overview	Dianne Murphy, MD Director, Office of Pediatric Therapeutics OC, FDA
8:20	Surveillance Data on Influenza Pediatric Deaths and Central Nervous System Adverse Events	David Shay, MD, MPH Influenza Division National Center for Immunization and Respiratory Disease, CDC
9:05	<i>Clarification Questions</i>	
9:20	<b>Tamiflu (oseltamivir)</b> – Japanese Scientist – Historical Perspective on Influenza Encephalitis, Encephalopathy in Japan and the Therapeutic Approach	Nobuhiko Okabe, MD, PhD, Director Infectious Disease Surveillance Center National Institute of Infectious Diseases, Japan
10:05	<i>Clarification Questions</i>	
10:20	Break	
10:30	<b>Tamiflu (oseltamivir)</b> – Brief Summary of Regulatory History and Update on Neuropsychiatric/Behavioral Adverse Events	Linda Lewis, MD, Medical Officer Division of Antiviral Products Office of New Drugs, CDER, FDA
11:00	<b>Tamiflu (oseltamivir)</b> – Safety Update on Pediatric deaths and Neuropsychiatric Events; Review of Neuropsychiatric Events with Other Antiviral Products	Adrienne Rothstein, PharmD, Safety Evaluator Division of Drug Risk Evaluation, Office of Surveillance and Epidemiology, CDER, FDA
12:00PM	<i>Clarification Questions</i>	
12:15	Lunch	
1:00	<i>Open Public Hearing</i>	
2:00	<b>Tamiflu (oseltamivir)</b> – Sponsor Presentation	Roche Representative
2:45	<i>Clarification Questions</i>	
3:00	Relenza (zanamivir) – Sponsor Presentation	GSK Presentation

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- 3:30      *Clarification Questions*
- 3:45      Break
- 4:00      Committee Deliberation and Recommendations
- 5:00      Adjourn

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